

## COMPACT ORONASAL PATIENT INTERFACE

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/533,214, filed December 31, 2003, which is incorporated herein in its entirety.

### FIELD OF THE INVENTION

[0002] The present invention relates to a patient interface for use between a patient and a structure to deliver a breathable gas to the patient, such as is used in gas delivery systems for respiratory therapy. Examples of such therapy are Continuous Positive Airway Pressure (CPAP) treatment, assisted respiration or Non-Invasive Positive Pressure Ventilation (NIPPV).

### BACKGROUND OF THE INVENTION

[0003] Comfort and effectiveness remain a continuing challenge for engineers and designers of the interface between a mechanical ventilator and a patient. Such patient interfaces are currently employed for a variety of purposes including the delivery of non-invasive ventilation or for the delivery of pressurized air to persons who suffer from sleep disordered breathing conditions such as Obstructive Sleep Apnea (OSA). In non-invasive positive pressure ventilation, a supply of air at positive pressure is provided by a blower to a patient interface through an air delivery conduit. The patient interface may take the form of a nasal mask, nose & mouth mask, full face mask or nasal prongs.

[0004] A mask may comprise (i) a rigid or semi-rigid portion which attaches directly to the air delivery conduit and (ii) a soft patient contacting portion. The rigid or semi-rigid portion, known as a shell or frame, may define a nose-receiving cavity, or a mouth covering chamber.

Other forms of patient interface, such as nasal cannulae, comprise a pair of nasal prongs, nasal inserts or nozzles.

[0005] The soft patient contacting portion is typically known as a cushion or membrane and is generally shaped during manufacture to match the facial contours of a patient in order to provide the optimum seal.

[0006] An inherent characteristic of patient interfaces such as nasal masks or nozzle assemblies is that they do not seal the mouth region. A number of patients thus find that during sleep when muscles relax, mouth leak may occur. Alternatively some patients are naturally mouth breathers and thus find a nasal patient interface ineffective. Mouth leak is undesirable as among other difficulties, it may result in noise, increased treatment pressure to compensate for the leak or an increased load on the nasal passages and potentially nasal obstruction or a runny nose.

[0007] Patient interfaces such as full face masks or nose and mouth masks address this issue by sealing around both the nose and the mouth. Since nasal bridge anthropometry varies greatly between patients, the soft patient contacting portion or cushion must adapt to the shapes of individual patients. Typically this is not achieved for the entire range of patients and some form of leak occurs. The problem is heightened during sleep when the jaw moves and the head position changes. This action can often serve to dislodge the mask and cause leak. Since leak can be noisy and results in less-effective treatment, users often compensate by tightening the headgear more than is required. This is detrimental for patient comfort and can cause skin breakdown.

[0008] A further problem encountered by patients who are using full face, nasal or nose and mouth masks is that the portion of the patient interface that seals around the nasal bridge prevents the patient from wearing spectacles. Additionally it may give the sensation of being

closed in, leading to a feeling of claustrophobia, particularly when combined with a mouth-sealing portion. A further disadvantage is that any leaks that may occur can affect the sensitive area surrounding the eyes.

[0009] One form of nasal assembly known as a nasal puff is described in U.S. Patent No. 4,782,832 (Trimble et al.). This device has a pair of nasal puffs together with a plenum chamber held in place with a harness assembly adapted to be worn over the head of the patient. The device does not provide a mouth seal.

[0010] Another form of known nozzle assembly is described in U.S. Patent No. 6,431,172 (Bordewick et al.). The patent discloses a device with nares elements mounted on an inflatable plenum chamber. Again this does not provide any structure for sealing the mouth.

[0011] One typical example of a known nasal mask is described in U.S. Patent No. 5,243,971 (Sullivan et al.). This has a ballooning seal in order to fit the patient's nose and facial contours but does not provide a mouth seal. The contents of this patent are hereby incorporated by cross-reference.

[0012] International publication number WO 01/97893 A1 (Frater et al.), the content of which is hereby incorporated by cross-reference, describes a mask system for delivering air to a user including a suspension mechanism. This suspension mechanism allows relative movement between a face-contacting portion and a mask shell.

[0013] A known example of a full face mask is described in U.S. Patent No. 6,513,526 B2 (Kwok et al.), incorporated herein by reference in its entirety. Whilst providing a facial contour and sealing mechanism that incorporates both the nasal and mouth, this mask cannot flex to adapt to changes in jaw movement and head position throughout the night.

[0014] A known example of a nose and mouth mask is described in U.S. Patent No. 5,560,354 (Berthon-Jones et al.), the content of which is hereby incorporated by cross-reference.

[0015] U.S. Patent Publication No. 2002/0069872 A1 (Gradon et al.) describes a mouthpiece which seals the oral cavity against 'mouth leak'. This mouthpiece includes both intra-oral and extra-oral sealing means and can be kept in place without the need for straps. International patent WO 01/95965 (Gradon et al.) describes a similar mouthpiece for supplying humidified gases to a user.

[0016] U.S. Patent No. 6,571,798 B1 (Thornton) describes an oral device for improving a patient's breathing together with a connecting post that provides a standard interface to a CPAP patient interface. The oral device is said to extend the lower jaw of the patient and thus open the breathing passage. The oral device is clenched between the teeth which may lead to discomfort and if mask pressures are high can lead to the slow creep of gums around the teeth due to the sustained load..

[0017] U.S. Patent No. 1,873,160 (Sturtevant) describes a cylindrical air chamber held in position by a mouth portion that extends between the lips and teeth. The mouth portion may prove irritating and lead to discomfort when used for long periods.

[0018] A problem with patient interfaces which incorporate oral appliances is that they can be uncomfortable for patients. Therefore, a need has developed in the art to address the problems of the prior art.

## SUMMARY OF THE INVENTION

[0019] In accordance with a first aspect of the invention there is provided a comfortable, effective patient interface which provides a supply of air or breathable gas to a patient's nasal passages and which prevents or reduces mouth leak.

[0020] In accordance with a second aspect of the invention there is provided a patient interface which can accommodate movement of the jaw of the patient.

[0021] In accordance with another aspect of the invention there is provided a patient interface that provides an effective seal with both the patient's mouth and the patient's nasal passages.

[0022] In one form the invention comprises a mouth covering chamber, a nozzle assembly and a structure to provide flexibility therebetween.

[0023] Another aspect of the invention relates to reducing contact area when compared to most known full face masks. This allows a far reduced headgear tension to be applied, significantly improving patient comfort. Patient comfort is further enhanced since the patient is less likely to feel claustrophobic, particularly with the removal of any mass that is close to the eyes.

[0024] In accordance with another aspect of the invention there is provided a patient interface adapted to connect to an air delivery conduit.

[0025] In accordance with another aspect of the invention there is provided a patient interface comprising a first chamber which incorporates a mouth covering chamber, a second chamber which incorporates a nozzle assembly and a flexible element connecting the first and second chambers.

[0026] In accordance with another aspect of the invention there is provided a patient interface comprising a mouth covering chamber, a pair of nozzles and a flexible attachment member therebetween.

[0027] In accordance with yet another aspect of the invention there is provided a patient interface comprising a mouth covering chamber and a pair of nozzles flexibly attached thereto. The mouth covering chamber incorporates a rigid portion defining the mouth covering chamber and a resilient or compliant patient-contacting portion. The pair of nozzles are mounted upon the patient-contacting portion.

[0028] In accordance with yet another aspect of the invention there is provided a patient interface comprising a mouth receiving assembly and a pair of nozzles flexibly attached thereto. The mouth receiving assembly incorporates a rigid portion defining a mouth covering chamber, a gusset portion and a patient-contacting portion. The pair of nozzles are mounted upon a flexible component of the patient-contacting portion.

[0029] In accordance with yet another aspect of the invention there is provided a patient interface with a strap routed around the top of the ears.

[0030] These and other aspects of the invention will be described in or apparent from the following detailed description of preferred embodiments, in which like elements designate like parts.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0031] Figs. 1a-d show a dual chamber patient interface in accordance with a first embodiment of the invention;

[0032] Figs. 1e-1h illustrate various embodiments as to connection between the upper and lower chambers;

[0033] Figs. 2a-c show a dual chamber patient interface in accordance with a second embodiment of the invention;

[0034] Figs. 3a-c show a dual chamber patient interface in accordance with a third embodiment of the invention;

[0035] Figs. 4a-c show a single chamber patient interface in accordance with a further embodiment of the invention;

[0036] Figs. 5a-d show front and rear views of a further embodiment of the invention.

[0037] Figs. 6a-b show a single chamber patient interface with mouth gusset portion in accordance with a further embodiment of the invention;

[0038] Figs. 7a-b show views of a single chamber patient interface with mouth gusset portion in accordance with a further embodiment of the invention;

[0039] Figs. 7c-f show views of an alternative embodiment of a single chamber patient interface in accordance with a further embodiment of the present invention;

[0040] Fig. 8 shows a patient interface in accordance with an embodiment of the invention connected to a headgear routed around the top of the ears;

[0041] Fig. 9 shows a patient interface in accordance with an embodiment of the invention connected to different forms of headgear routed around the top of the ears;

[0042] Figs. 10-12 illustrate various headgear arrangements according to further embodiments of the invention;

[0043] Figs. 13-18d illustrate another embodiment of a single chamber patient interface;

[0044] Figs. 19-24d illustrate another embodiment of a single chamber patient interface;

[0045] Figs. 25a-25e illustrate other embodiments of a single chamber patient interface;

[0046] Figs. 26-28 illustrate another embodiment of a single chamber patient interface with no nozzles;

[0047] Figs. 29 and 30 illustrate embodiments of a single chamber patient interface with blocked nozzles;

[0048] Figs. 31-33c illustrate another embodiment of a single chamber patient interface with a gusset portion;

[0049] Figs. 34-38 illustrate embodiments of a single chamber patient interface with insertable nozzles;

[0050] Figs. 39-40 illustrate embodiments of a patient interface with a mouth appliance;

[0051] Figs. 41-42 illustrate an embodiment of a patient interface with a corrugated frame;

[0052] Figs. 43-56b illustrate embodiments of nozzle arrangements;

[0053] Figs. 57-62 illustrate embodiments of support members for nozzles;

[0054] Figs. 63-64 illustrate an embodiment of a patient interface with a boomerang-shaped cushion;

[0055] Fig. 65a-65c illustrates an embodiment of a patient interface with an extended frame;

[0056] Figs. 66a-67 illustrate an embodiment of a patient interface with an insertable anti-asphyxia valve; and

[0057] Figs. 68-80 illustrate embodiments of headgear assemblies.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0058] Figs. 1a-1d illustrate a first embodiment of the present invention. As shown in Fig. 1a, a headgear assembly 1 includes a patient interface having a dual chamber assembly 10 including an upper chamber 12 and a lower chamber 14. As shown in Fig. 1a, the lower chamber 14 is in a disconnected position, while Figs. 1b-1d shown the upper and lower chambers in a connected position.

[0059] Referring to Fig. 1a, the upper chamber 12 includes a nozzle assembly 16 supported by a frame including a first connector on each lateral end thereof, as described in U.S. Patent Application No. 10/781,929, filed February 20, 2004 and incorporated herein by reference in



its entirety. The nozzle assembly 16 is secured to the frame via a clip 18 which in this embodiment supports a pressure measurement port 20. The nozzle assembly 16 may include a pair of nozzles 17 (see Figs. 1c and 1d).

[0060] One or more inlet conduits 22 is supplied with breathable gas under pressure via a joint 24 coupled to an air delivery tube, which in turn is communicated with a blower or air delivery device. The lower chamber 14 is connected to the joint 24 via an inlet conduit 35. The joint 24 may include three branches (see Fig. 1b) for connection to the inlet conduits 22 and 35.

[0061] Each inlet conduit 22 is connected to an elbow connector 26, which is preferably connected to yoke 28 of strap 30 of headgear assembly 31 via a locking portion 32. Each elbow connector 26 is coupled to a second connector 34. Each respective first connector of the frame may be selectively rotated with respect to the second connectors 34 to allow the nozzle assembly 16 to be adjusted according to patient requirements, to achieve the best fit.

[0062] As best shown in Fig. 1a, where the upper and lower chambers are disassembled, a first portion 36 of the lower chamber 14 may be connected to a second portion 37 of the upper chamber 12. Connection may be achieved via a conduit 41 (See Fig. 1e), or preferably a flexible element that connects the upper chamber 12 to the lower chamber 14. The flexible element may comprise one or more thin silicone conduits through which air can pass. It may take the form of any other flexible element through which air can pass however, examples including a spring 43 (Fig. 1f), bellows 45 (Fig. 1g) or piston mechanism 47 (Fig. 1h). The flexible element provides a range of adjustment to adapt to the different geometry of a wide range of patients and in addition allow for any movement of their jaw and head position during sleep. The conduit need not be flexible if adjustment can occur via flexibility of the cushions of the upper and lower chambers.

[0063] Connection between the upper and lower chambers may take several forms, keeping in mind that one main purpose is to maintain the position of the upper chamber 14 relative to the patient's mouth. To that end, the connection may take the form of a mechanical fastener, such as VELCRO®, snaps, connectors, etc. For example, the top or second portion 37 of the upper chamber 14 may include a hook portion of VELCRO®, while the bottom or first portion 36 of the upper chamber 12 may include the loop portion of VELCRO®. In other forms, the connection may be provided via metal or plastic rivets and/or by use of adhesives. In the case of rivets, flexibility could be provided by virtue of the compliant and flexible portions of the cushions of the respective upper and lower chambers that are fastened together. In other forms, the lower chamber 14 may be connected to a portion of the headgear or to the inlet tubes 22. Moreover, it is not necessary that air can pass between the upper and lower chambers 12, 14, as each has an independent source of pressurized air.

[0064] As shown in figures 1a-1d, the lower chamber 14 includes a rigid polycarbonate frame 38 which defines a mouth covering chamber 40 (see Fig. 1c) and a soft (e.g., compliant, resilient) silicone cushion 42 which contacts the patient and forms a seal. The lower chamber 14 closely resembles the mouth chamber and mouth cushion described in U.S. Patent No. 5,560,354, the contents of which are hereby incorporated by cross-reference. However it may take a variety of forms, such as described in U.S. Provisional Patent application No. 60/483,622 filed 1 July 2003. The cushion 42 may be attached to the frame 38 by connecting a base edge of the cushion 42 to the frame 38, e.g., via adhesives and/or a tongue and groove arrangement. In another form, connection may be achieved by stretching the cushion 42 over the outer edge of the frame 38.

[0065] The inlet conduit 35 is structured to deliver breathable gas into the lower chamber 14. The inlet conduit 35 may be inserted into an aperture of the frame 38, in which case the tube

35 may be held in place by friction alone, as best shown in Figs. 1b and 1d. Alternatively, the inlet conduit 35 may be connected to a swivel assembly (not shown) which in turn is connected to the frame 38. In another alternative, one or more suitable headgear straps (not shown) can be used to support the lower chamber 14 such that it can move or pivot relative to the upper chamber without the need for connection thereto or a flexible element.

[0066] Figures 2a and 2b show a second embodiment of the invention. In this embodiment, the lower chamber 14 does not have a direct inlet conduit, like the inlet conduit 35 in Fig. 1a, but instead the air is directed to the upper chamber 12 via the inlet conduits 22 only. Air travels through the flexible element, i.e., through first and second surfaces 36 and 37, from the upper chamber 12 to the lower chamber 14, for example, thus allowing both nose and mouth breathing. Fig. 2b best showed the position where the flexible element would be located between the first and second surfaces 36, 37.

[0067] Fig. 2c shows one example of how the upper and lower chambers 12, 14 may communicate with one another. A mechanical fastener 90 includes first and second parts 92 and 94. The first part 92 may take the form of a thin plate attached to an inside surface 37a of the second part 37 formed on the upper chamber 12. The first part includes an aperture 96. The second part 94 may include a thin plate positioned on the inside surface 36a of the first part 36 formed on the lower chamber 14. The second part 94 includes one and preferably a plurality of arms 98 extending through the upper and lower chambers 12, 14. The arms 98 are resiliently flexible so that shoulder 100 on each arm 98 may be secured against a top surface 92a of the first part, thereby locking the entire assembly together while allowing gas to flow between the upper and lower chambers 12, 14. The arms 98 may be formed so as to cut through the upper and lower chambers 12, 14 upon assembly, thereby creating the through hole. The assembly may provide for multiple holes if desired.

[0068] In Figs. 2a and 2b, a plug 48 covers an aperture of the frame 38 where an inlet conduit could be placed. Therefore, the joint 24 in Fig. 1a need not include a separate branch for the conduit 35, or the branch could be plugged.

[0069] In a third embodiment of the invention, as shown in Figs. 3a and 3b, inlet air is directed directly to the lower chamber 14 through a swivel assembly 50. The upper chamber 12 does not have any inlet conduits but instead the air is directed to the upper chamber 12 by traveling through a conduit extending from the first surface 36 to the second surface 37. The use of a swivel assembly 50 has the advantage that the inlet conduit (not shown, but connected to end 52 of swivel assembly 50) can be routed from any direction. Further, nozzle assembly 16 need not be provided with second connectors 34 and elbow connectors 26 as shown in Fig. 1a. Instead, a pair of plugs 54 may be placed into each end of the nozzle assembly 16, as described in U.S. Patent Application No. 10/781,929, filed February 20, 2004 and entitled "Nasal Assembly", incorporated herein by reference in its entirety.

[0070] Figures 4a-c schematically show a fourth embodiment of the invention. In this embodiment, the mouth covering chamber 40 and the nozzle assembly 16 form one chamber with inherent flexibility of the soft silicone cushion 42 upon which the nozzles 17 are mounted providing for movement and changes in alignment between the two. This embodiment of the invention achieves the advantage of minimizing the volume of the patient interface which is positioned between the nares and the upper lip.

[0071] Figs. 5a-5d illustrate yet another embodiment of the invention. As can be seen from Fig. 5a, a swivel assembly 50 provides air from an air delivery tube (not shown) and supplies it to the mouth covering chamber 40 (best shown in Fig. 5b). The cushion 42 is connected to the rigid frame 38 of the mouth covering chamber 40 via a cushion clip 56. As best shown in Fig. 5b, the nozzles 17 are connected or provided directly to the outer face contacting portion

of the cushion 42 which takes the form of a thin silicone membrane 58. The membrane 58 performs the dual function of forming a seal around the lips of a patient and additionally supporting the nozzles 17. The inherent flexibility of the membrane 58 provides a range of adjustment to adapt to the different geometry of a wide range of patients and in addition allows for any movement of their jaw and head position during sleep. It should be noted that whilst this embodiment describes nozzles 17 of a similar form to those disclosed in US Patent application No. 10/781,929 filed 20 February 2004, the contents of which are hereby incorporated by cross-reference, they may take the form of any nasal prongs insertable into each nare. As shown in Fig. 5d, the patient interface can easily be attached via clips 60 to a headgear assembly 31 in order to secure the patient interface to the patient. The headgear 31 includes an intermediate strap 31a extending between clip 60 and connector 33. The clip 60 and its connection to frame 30 resemble the clip/frame described in U.S. Patent Application No. 10/655,603, filed September 5, 2003, incorporated herein by reference in its entirety.

**[0072]** Figures 6a-b schematically illustrate a fifth embodiment of the invention. In this embodiment the patient interface includes a mouth covering chamber 40 incorporating a rigid frame 38, a gusset portion 62 and a soft cushion 42. The nozzles 17 are connected directly to the outer face contacting portion of the cushion 42 which takes the form of a thin silicone membrane 58. The gusset portion 62 includes a flexible membrane and has a first side attached to the frame 38 and a second side attached to the cushion 42, as shown in Fig. 6b. Pressure within the patient interface acts upon the increased surface area of the gusset portion 62 projected on the patient's face so as to provide a sealing force for the soft cushion 42 against the patient's face. In addition the gusset portion 62 acts to effectively isolate or decouple the rigid frame 38 from the soft cushion 42. In these respects, the gusset portion 62 acts in a similar manner to that described in International publication number WO 01/97893

A1 (Frater et al.), the content of which is hereby incorporated by cross-reference in its entirety.

[0073] Due to its location between the cushion 42 and the frame 38, the gusset portion 62 also acts to decouple the nozzles 17 mounted upon the soft cushion 42 from the rigid frame 38. This provides further flexibility within the patient interface which has the advantages previously described of allowing the interface to adjust to the geometry of different patients and allowing for any jaw or head movement during sleep. A further advantage of the gusset portion 62 is that it allows the face contacting portion, e.g., membrane 58, of the cushion 42 increased freedom to deform in accordance with the contours of the mouth region than does a direct connection between the cushion 42 and rigid frame 38. Thus the cushion 42 may "wrap around" the mouth region as required.

[0074] The gusset portion 62 of the embodiment shown in figures 6a and 6b is a partial gusset portion in that it is arranged at the chin portion of the mouth covering chamber 40. Alternatively the gusset portion 62 may fit around the entire circumference of the rigid frame 38. An embodiment of this is shown in figures 7a-c. As can be seen from Fig. 7a, the embodiment includes an inlet swivel assembly 50, a frame 38, a gusset portion 62 and a soft cushion 42 with nozzles 17 mounted thereon.

[0075] Fig. 7b shows the components disassembled, although the swivel assembly 50 and frame 38 are shown in an assembled state that could be disassembled in an alternative embodiment. The headgear clips 60, cushion clip 56 and cushion 42 with gusset portion 62 can also be seen in Fig. 7b. The clip 56 may include one or more resilient tabs 57 that engage with corresponding recesses 59, one of which is shown on frame 38.

[0076] Two alternative cushions, 42A and 42B without gussets are displayed in Fig. 7b. It should be noted that each of the nozzles 17 on cushion 42B includes a simple mound rather

than containing a single flexible pleat as do the nozzles on cushion 42 and cushion 42A. The nozzles 17 may also include a plurality of corrugations and in general the nozzles may take the form of a nasal puff as described in U.S. Patent No. 4,782,832 (Trimble et al), or as in other known nasal cannulae, such as prongs that extend into the nares. Further nozzle alternatives are described in U.S. Application No. 10/781,929, filed February 20, 2004 and entitled "Nasal Assembly."

[0077] Figures 7c-7f show an alternative embodiment of a patient interface assembled to a headgear assembly 31 via clip 60 that is selectively adjustable in a rotational sense with respect to yoke 31 attached to strap 30, as described in U.S. Patent Application No. 10/391,440, filed March 19, 2003, incorporated herein by reference in its entirety. Each clip 60 includes opposed arms 64 that may resiliently flex towards one another to allow engagement and disengagement of claws 66 formed on arms 64. The claws 66 may lockingly engage with corresponding structure or a receptacle 68 formed on or as part of frame 38. In this embodiment, the receptacle 68 may be moved, flexed or pivoted with respect to a portion 38a of the frame 38, e.g., along pivot axis 70. Fig. 7d shows the clips 60 in different angular positions.

[0078] Fig. 7e is an exploded view of clip 60, receptacle 68 and portion 38a of frame 38. The portion 38a may be attached to (e.g., via glue) or formed as an integral part of the frame 38. The receptacle 68 includes side chambers 68a for receiving claws 66 and a central chamber 68b for receiving central tab 61 of clip 60. The receptacle 68 may be attached to portion 38a, e.g., via a pin and slot assembly. For example, the receptacle 68 may include opposed arms 69 each including a pin 71. Each pin 71 can be received within an end 73 of a C-shaped channel 75. At least one of the arms 69 or the C-shaped channel 75 may flex to allow

assembly and disassembly. Of course, other arrangements for allowing relative movement are possible.

[0079] Alternative headgear may be used, i.e., this embodiment is not limited to the headgear assembly shown in Fig. 7c. Vents 72 for the removal of excess carbon dioxide are shown in Fig. 7c. The vents 72 may be formed on an elastic insert, as described in U.S. Patent No. 6,561,190, incorporated herein by reference in its entirety. Fig. 7f shows an enlarged patient-side view of the cushion 42 in isolation.

[0080] Fig. 8 shows an alternative form of headgear with an occipital strap 74, a coronal strap 76 and a depending strap 78 that is routed to the top of the ears. The headgear straps 74, 76, 78 may be rigid or may be constructed from a laminated foam material such as Breath-O-Prene™. In one form the headgear straps may be constructed from a combination of a soft comfortable material, such as Breath-O-Prene and a stiffening yoke 28 constructed from a polymer, such as nylon, as described in International Patent Application PCT/AU03/00458. Angular adjustment between the rigid frame 38 and the headgear, such as that may be achieved via the arrangement shown in Fig. 7c.

[0081] Figures 9-12 show the patient interface supported by spectacles-type headgear 80. One strap 82 is used as a hook mechanism behind the ear. The strap 82 may be extended to wrap around the head and apply a force inwards towards the head, as shown in Fig. 9, or the wrap around portion may be eliminated as shown in Fig. 10. Fig. 11 shows an additional stabilizing band 84 around the neck. The headgear straps may be formed of any suitable material such as textile, plastic or semi-rigid assemblies. The headgear assembly has the advantage that it covers the minimum head area and therefore is more comfortable than many traditional designs. In order to improve patient comfort, the headgear may also require



adjustment to suit the head circumference and ear height. It may also be applied to alternative forms of patient interface such as nasal prongs or nose masks.

[0082] Figs. 13-18d illustrate another embodiment of a patient interface. As illustrated, the patient interface includes a cushion 42 and a pair of nozzles 17 flexibly mounted to the cushion 42. The patient interface is formed as a one-piece structure such that the cushion 42 is integrally formed in one-piece along with the nozzles 17. For example, the cushion 42 and nozzles 17 may be formed in an injection molding process as is known in the art. Also, the cushion 42 and nozzles 17 form one chamber with flexibility between the cushion 42 and nozzles 17 to provide for movement and changes in alignment between the two.

[0083] The cushion 42 includes a non-face-contacting portion and a face-contacting portion. The non-face-contacting portion is structured to be removably and replacably attached to a rigid frame associated with the air delivery tube. The non-face-contacting portion may be removably and replacably attached to the frame in any suitable manner, e.g., cushion clip, friction or interference fit, and/or tongue-and-groove arrangement, as is known in the art. However, the non-face-contacting portion may be permanently attached to the frame, e.g., by glue and/or mechanical fastening means.

[0084] As best shown in Figs. 15 and 18a-18d, the face-contacting portion of the cushion 42 includes a side wall 51, a pair of underlying support rims 53 extending away from the side wall 51, and a membrane 58 provided to substantially surround the rims 53 and provide a sealing structure for the face contacting portion. The side wall 51 and rims 53 provide a support structure for the face contacting portion. Also, as best shown in Fig. 16, the face-contacting portion is contoured to follow generally the curvature of the patient's face.

[0085] The membrane 58 is structured to form a seal around the lips of a patient. In the illustrated embodiment, the membrane 58 has a substantially flat profile. In use, the edge 61

of the flat-profiled membrane 58 is the first point of contact with the patient's face. As the membrane 58 comes more into contact with the patient's face, the membrane 58 conforms to the patient's face with good contact at the inner edge 61 thereof, which reduces the possibility of pressurized air coming between the skin and the edge 61, thereby improving the integrity of the seal. Also, the edge 61 of the membrane 58 contacts the face and fully extends or stretches the membrane 58, thereby eliminating any wrinkles. A more rounded membrane profile provides a tangential contact with the patient, potentially providing a leak path under the membrane when air pressure is applied. Further, the membrane 58 extends further than the edges of the rims 53 to prevent the rims 53 from being a source of irritation (e.g., see Fig. 18b).

[0086] The inner edge of the membrane 58 defines an aperture 55 that receives the patient's lips. As best shown in Fig. 14, the aperture 55 has a generally oval shape. However, the aperture 55 may have any other suitable shape to accommodate variations in the shape of a patient's mouth.

[0087] For example, Figs. 19-24d illustrate another embodiment of a patient interface.

Similar elements are indicated with similar reference numerals. As illustrated, the upper edge of the aperture 55 has an arcuate protruding portion. Also, as shown in Figs. 20 and 21, the upper side of the side wall has an arcuate configuration that corresponds with the arcuate configuration of the upper edge of the aperture 55. Thus, the plan profile of the cushion 42 shown in Figs. 20 and 21 is curved and has a shape similar to a smile. This configuration helps stability by more closely following the patient's facial geometry and prevents roll since the cushion 42 is higher at the sides. That is, the cushion shown in Fig. 20 has a greater height than the cushion shown in Fig. 14, which helps with stability. However, the shorter height of the cushion shown in Fig. 14 has a shorter profile and is therefore less obtrusive to

the patient. For example, the cushion in Fig. 20 may have a height of about 60 mm and the cushion in Fig. 14 may have a height of about 50 mm. However, the cushion may have any other suitable height. The cushion 42 also has a membrane 58 with a substantially flat profile (e.g., see Figs. 24a-24c), which provides an enhanced seal as described above.

[0088] As best shown in Fig. 15, the rims 53 are preferably provided on lateral sides of the side wall only 51. The rims 53 add rigidity to the membrane 58 at the sides of the patient's mouth or cheeks. As illustrated, each rim 53 has a general C-shape and extends inwardly into the cavity of the cushion 42. While it is preferable that the membrane 58 be thinner than the rim 53, they could have the same thickness. For example, in Figs. 18a, 18c, 24a, and 24c, the side wall thickness may be about 3.20 mm, which tapers to about 0.50 mm at the edges of the membrane. In Figs. 18b and 24b, the side wall thickness may be about 3.20 mm, which tapers to about 0.50 mm at the edges of both the rim and the membrane. However, the side wall, rim, and membrane may have any other suitable thicknesses.

[0089] As shown in Figs. 18b and 18d, the inside surface of the membrane 58 is spaced from the outside surfaces of the rims 53 so that the membrane 58 can accommodate small variations in the shape of the patient's mouth without undue force and can account for small movement of the patient interface relative to the patient during use, while maintaining an effective seal. The spacing between the rim 53 and the membrane 58 may have any suitable size. Moreover, the rim 53 may extend around the entire perimeter of the side wall, or may have any other suitable configuration to support the membrane 58.

[0090] In the illustrated embodiment, the face-contacting portion of the cushion 42 has a double-walled construction, i.e., membrane and rim, in the region of the cheeks and a single-walled construction, i.e., membrane, under the nozzles 17 and in the region of the chin and/or lower lip. The single wall construction at the top and bottom of the cushion 42 helps to

accommodate high landmarks, e.g., pointed chin, by allowing the center of the cushion 42 to flex. This flexibility accommodates more patients with the same cushion 42. Also, the single wall construction under the nozzles 17 alleviates space constraints and potential occlusion of the nasal air path by a rim. However, the cushion 42 may have any other suitable construction, e.g., single walled, triple walled or more walled construction, in any suitable region of the cushion 42, e.g., cheek, chin, under nozzles. For example, Fig. 25a illustrates an embodiment of a patient interface substantially similar to the patient interface shown in Figs. 13-18d. In contrast, the patient interface includes a rim 53 that extends around the entire perimeter of the cushion 42 as indicated by the dashed line. Also, the rim 53 could be completely removed. Figs. 25b-25e illustrates an embodiment of a patient interface substantially similar to the patient interface shown in Figs. 13-18d (nozzles omitted for clarity purposes). In contrast, the side wall 51 of the cushion 42 has a slightly different perimeter geometry. The cushion 42 also has a membrane 58 with a substantially flat profile (e.g., see Figs. 25c-25e), which provides an enhanced seal as described above.

[0091] The side wall of the cushion 42 supports the pair of nozzles 17. Similar to the above embodiments, the nozzles 17 may have a similar form to those disclosed in U.S. Patent application No. 10/781,929 filed 20 February 2004, the contents of which are hereby incorporated by cross-reference, however they may take the form of any nasal prongs insertable into each nare.

[0092] As illustrated, each nozzle 17 includes a conduit 19 that interconnects each nozzle 17 with the cushion 42 and allows breathable gas to pass from the chamber defined by the cushion 42 to the nozzles 17. As shown in Figs. 14, 16 and 17, the conduits 19 and nozzles 17 attached thereto are angled with respect to the side wall to properly position the nozzles 17 with the nasal passages of the patient. For example, the angle  $\theta$  in Figs. 14 and 20 is referred

to as the alar angle, the angle  $\alpha$  in Figs. 16 and 22 is referred to as the nostril angle, and the angle  $\beta$  in Figs. 17 and 23 is referred to as the naso-labial angle. As illustrated, the angle  $\theta$  is substantially the same in Figs. 14 and 20, the difference being that the angle  $\theta$  in Fig. 14 is defined by the nozzles 17 whereas the angle  $\theta$  in Fig. 20 is defined by the side wall 51. The angles  $\theta$ ,  $\alpha$ , and  $\beta$  may have any suitable value and may be determined from anthropometric data. For example, the angle  $\theta$  may be between  $60^\circ$ - $180^\circ$ , the angle  $\alpha$  may be between  $0^\circ$ - $120^\circ$ , and the angle  $\beta$  may be between  $40^\circ$ - $140^\circ$ . These angles are merely exemplary and should not be limiting. Also, the nozzles 17, conduits 19, and side wall 51 may have any suitable configuration to properly position the nozzles 17 with respect to the nasal passages of the patient.

[0093] Also, the conduits 19 may have different lengths to accommodate different patients. For example, the conduits 19 illustrated in Figs. 13-17 are longer than the conduits 19 illustrated in Figs. 19-23. The longer conduits of Figs. 13-17 provide more nozzle flexibility, whereas the shorter conduits of Figs. 19-23 allow more direct transfer of forces from the side wall support to the nozzles. The conduits 19 may have any suitable length and may be suitably varied to accommodate various patients, e.g., with varying length between the patient's nose and upper lip. For example, in an embodiment, the nozzles 17 are about 8 mm long, which allows good flexibility and articulation while still allowing the nozzles 17 to be loaded adequately to effect seal.

[0094] Figs. 26-28 illustrate an embodiment of a patient interface wherein the nozzles have been removed so that the patient interface includes a cushion 42 only. The cushion 42 may have a structure similar to the cushions described above, e.g., side wall 51, a pair of rims 53 extending away from the side wall 51 in the cheek regions, and a membrane 58. However, the cushion 42 may have any other suitable structure to seal around a patient's mouth.

[0095] Figs. 29 and 30 illustrate embodiments of a patient interface that include a cushion 42 and a pair of nozzles 17 that are blocked from fluid communication with the chamber defined by the cushion 42. In Fig. 29, the nozzles 17 are blocked at entrance to the cushion 42. That is, the upper portion of the side wall 51 is not provided with any openings that communicate with the nozzles 17. In Fig. 30, the nozzles 17 are blocked at the nozzle tips. That is, the nasal opening of the nozzle 17 is blocked so that gas cannot pass through the nozzles 17. The pressure within the nozzles 17 aids the seal within the nasal passages of the patient. In another embodiment, a set of plugs may be inserted into the nozzles 17, e.g., at the top or bottom of the nozzles, to block nasal flow. In these embodiments, the nozzles 17 simply seal the patient's nasal passages, and gas is delivered to the patient's mouth only. The blocked nozzles may also serve to stabilize the cushion and help with alignment.

[0096] Figs. 31-33c illustrate an embodiment of a patient interface that includes a cushion 42 and a pair of nozzles flexibly mounted to the cushion 42 (nozzles omitted for clarity purposes). As illustrated, the cushion 42 includes a side wall 51 incorporating a gusset portion 62, a pair of rims 53 extending away from the side wall 51, and a membrane 58 to substantially surround the rims 53 and provide a sealing structure for engagement with the patient's face.

[0097] Similar to the embodiments in Figs. 13-24d, the rims 53 are provided on the lateral sides of the side wall 51 only (e.g., see Figs. 31 and 33b). However, a rim may be provided around the entire perimeter of the side wall, or at any other suitable portion of the side wall, e.g., chin portion of the cushion. Also, similar to the embodiments in Figs. 13-24d, the side wall thickness may be about 3.20 mm, which tapers to about 0.50 mm at the edges of both the rim and the membrane. The thickened side wall helps to support the nozzles in proper position.

[0098] As best shown in Figs. 32, 33b, and 33c, the gusset portion 62 is provided on the lateral sides of the side wall 51 and the lower wall of the side wall 51 (adjacent the patient's chin). However, the gusset portion 62 may be provided around the entire perimeter of the side wall. Similar to the gusset portion described above in Figs. 6a and 6b, for example, the gusset portion 62 provides further flexibility within the patient interface to allow the interface to adjust to the geometry of different patients, allow for any jaw or head movement during sleep, and allow the membrane 58 of the cushion 42 increased freedom to deform in accordance with the contours of the mouth region without disturbing nozzle seal. Also, the gusset portion 62 could be replaced by a flexible spring, or any other suitable structure that would add flexibility.

[0099] Figs. 34-38 illustrate embodiments of a patient interface that include a cushion 42 and a pair of nozzles 17 that are selectively mounted to the cushion 42. Specifically, the nozzles 17 are formed separately from the cushion 42, and then secured to the cushion 42 to construct a patient interface with both cushion 42 and nozzles 17. This arrangement provides a greater scope of patient fitting by being able to select cushion size and nozzle size independently. Also, the nozzles 17 may be independently aligned with respect to the cushion 42 for optimal fit.

[00100] In each of the embodiments, each nozzle 17 includes a nozzle portion 21 that seals within a respective patient nasal passage and a base portion 23 that is mountable to the cushion 42. The side wall of the cushion 42 includes nozzle mounting portions 25 structured to mount a respective nozzle 17.

[00101] The nozzles 17 may be mounted to the cushion 42 in any suitable manner. For example, Fig. 34 illustrates an arrangement wherein the nozzle mounting portions 25 are in the form of inclined platforms 104 structured to support a respective nozzle 17 thereon. The

base portion 23 of the nozzles 17 may be secured to respective platforms 104 in any suitable manner, e.g., adhesive, male/female connection, etc.

[00102] Fig. 35 illustrates an arrangement wherein the nozzle mounting portions 25 provide substantially flat mounting surfaces structured to support a respective nozzle 17 thereon. The base portion 23 of the nozzles 17 are secured to respective surfaces via a male/female connection mechanism. For example, each base portion 23 may include a protrusion that is secured within a respective opening provided in the respective nozzle mounting portion 25 of the cushion 42. However, the nozzles 17 may be secured to the cushion 42 in any other suitable manner.

[00103] Fig. 36 illustrates an arrangement wherein the nozzle mounting portions 25 are in the form of cylindrical protrusions structured to engage within openings provided in the base portion 23 of respective nozzles 17. However, the nozzles 17 may be secured to the cushion 42 in any other suitable manner.

[00104] As shown in Figs. 35 and 36, the nozzles 17 are mounted to the cushion 42 such that the nozzles 17 can rotate independently to align each nozzle 17 with a respective one of the patient's nares. As shown in Fig. 36b, a ball-jointed insert 106 may be incorporated into the nozzles 17 to allow greater rotational and angular freedom and allow alignment in all directions. As shown in Fig. 38, the cushion 42 may include angular alignment marks 27 to align the nozzles 17 with respect to the cushion 42, which assists the patient in consistent set-up. The marks 27 may have any suitable configuration, e.g., detented.

[00105] Fig. 37 illustrates an arrangement wherein each nozzle mounting portion 25 provides an opening defined by edges having a stepped configuration. The base portion 23 of each nozzle 17 has an annular recess that receives the stepped edge of the opening therein, so as to secure each nozzle 17 within the respective opening. The stepped edge may include one



or more resilient protrusions (in dashed lines) to improve the seal between the cushion 42 and nozzles 17. Also, the stepped edge may have multiple steps to allow for selective height adjustment. However, the nozzles 17 may be secured to the cushion 42 in any other suitable manner. Also, the nozzle 17 illustrated in Fig. 37 includes a gusset portion 29 that adds flexibility and articulation of the nozzle 17 with respect to the cushion 42. It should be understood that one or more gusset portions 29 may be provided on each nozzle 17, and the gusset portion 29 may have any suitable configuration to improve nozzle flexibility.

[00106] The embodiments of Figs. 34-37 allow nozzles 17 to be interchanged for different size patient nares, which improves seal and patient comfort. Also, it should be understood that the nozzles 17 could be interchanged individually, or a single insert could be provided that contains both nozzles 17.

[00107] Figs. 39-40 illustrate embodiments of a patient interface that include a pair of nozzles 17 that are mounted to a mouth appliance 110, e.g., an appliance that sits within a patient's mouth. In the illustrated embodiment, the mouth appliance 110 provides a mouth seal by sandwiching the inside and outside of the patient's mouth. Specifically, the mouth appliance 110 includes a tongue depressor 112, a soft seal 114 that abuts against the inner surface of the patient's mouth, and a snap flap 116 that abuts against the outer surface of the patient's mouth to provide an endstop against the appliance being swallowed. An example of such mouth appliance is disclosed in WO200195965, the contents of which are hereby incorporated by cross-reference. The nozzles 17 are mounted to the mouth appliance 110 by a conduit 19 that allows gas to pass between the mouth appliance 110 and nozzles 17. The conduit 19 may have a flexible or rigid construction. As shown in the embodiment of Fig. 40, a mask system 118, e.g., similar to a diving mask, may be incorporated into the patient

interface to improve seal and to help locate the nozzles 17 with respect to the patient's nasal passages. Also, the tongue depressor 112 is optional and may be removed.

[00108] Figs. 41 and 42 illustrate an embodiment of a patient interface having a corrugated frame 38 and a cushion (not visible) with nozzles 17 mounted to the frame 38, or to the cushion. The corrugations in the frame 38 add flexibility to the frame 38 to allow the frame 38 to adjust to the facial geometry of different patients and to allow for any jaw or head movement during sleep. For example, the frame 38 may move downwardly for jaw dropping during sleep, and may move rearwardly for receding jaw (see arrows in Fig. 42). As illustrated, the corrugations are provided along a lower portion of the frame 38. However, the corrugations may extend across the entire frame 38. The movement may be accomplished via pivoting and/or sliding action of the corrugated frame about the sides of the frame. In this arrangement, the seal in the lower lip region is thus not compromised even if the jaw moves. Also, frame flexibility may be provided by other suitable structures, e.g., gusset portion provided in the frame. The frame 38 may be adjusted, e.g., by adjusting the tension in the lower straps of a headgear assembly 31. Further, the corrugated configuration may be incorporated into a full-face mask.

[00109] Also, the frame 38 is structured such that inlet conduits 22 are coupled to the sides of the frame 38 for delivering breathable gas into the patient interface. However, one or more inlet conduits 22 may be coupled to the frame 38 in any other suitable manner, e.g., to the front of the frame.

[00110] Figs. 43-46 illustrate embodiments of patient interfaces including a cushion 42 and a pair of nozzles 17 mounted to the cushion 42. The nozzles 17 are mounted to the cushion 42 to add flexibility to the nozzles 17 with respect to the cushion 42. For example, Fig. 43 illustrates nozzles 17 mounted within respective rounded recesses 120 or scalloped reliefs

provided in the side wall of the cushion 42. The depth of the recess 120 may be suitably modified to provide desired variations of flexibility. For example, the recesses 120 may be relatively deep for greater flexibility as shown in Fig. 44, or the recesses 120 may be relatively shallow for moderate flexibility as shown in Fig. 45. Fig. 46 illustrates an embodiment wherein a radial notch 122 is provided in the conduit 19 that interconnects each nozzle 17 with the cushion 42. The notch 122 adds flexibility to the conduit 19 which facilitates movement of the nozzle 17 with respect to the cushion 42.

[00111] Figs. 47-51 illustrate embodiments of nozzles 17 having a nozzle portion 21 and a conduit 19 that interconnects the nozzle portion 21 with the side wall of the cushion 42. As illustrated, the cross-sectional configuration of the conduit 19 may be varied to vary the flexibility of the nozzle 17. For example, Figs. 47 and 48 illustrate an embodiment wherein the conduit 19 has a substantially constant cylindrical cross-sectional configuration along its length. Figs. 49-51 illustrate an embodiment wherein the cross-sectional configuration of the conduit 19 varies along its length. As illustrated, the conduit 19 has an elliptical cross-sectional configuration near the nozzle portion 21 which continuously varies to a cylindrical cross-sectional configuration near the side wall of the cushion 42. Thus, the conduit has a "swept" cross-sectional configuration. In other embodiments, the nozzles 17 may include anatomically-shaped nozzle portions, and the nozzle portions may include openings that are off-center from the conduit opening. Preferably, the cross-sectional shape of the conduit and the nozzle opening are similar or the same, although dissimilar shapes are also possible. Also, the nozzles 17 may be structured to dilate the patient's nose similar to the structure shown in Fig. 18 of U.S. Patent No. 4,782,832, which is incorporated herein by reference.

[00112] Figs. 52-54 illustrate an embodiment of a patient interfaces including a cushion 42 and a pair of nozzles 17 mounted to the cushion 42. As illustrated, the nozzle conduits 19

have a concertina configuration, e.g., accordion-like, which adds flexibility to the nozzles 17 with respect to the cushion 42. Specifically, the concertina configuration allows both rotational and vertical adjustment of the nozzles 17 with respect to the cushion 42. For example, Fig. 53 shows a nozzle 17 in a neutral position, and Fig. 54 shows a nozzle 17 stretched and rotated with respect to the cushion 42. The concertina configured conduit 19 may be constructed from a soft silicone material or a stiffer material, e.g., drinking straw material, to allow articulation and extension. This configuration allows the conduits to be adjustably positioned in a number of different positions, and maintained in position during use. Also, the nozzles 17 may be integrally formed in one-piece along with the cushion 42, or the nozzles 17 may be formed separately from the cushion 42 and mounted thereto.

[00113] Figs. 55a-56b illustrate embodiments of nozzles 17 for use in a patient interface. As shown in Figs. 55a and 55b, each nozzle 17 may include a gusset portion 29 in the conduit 19 that interconnects the nozzle portion 21 with a cushion. The gusset portion may have any suitable width. For example, Fig. 55a illustrates a narrower gusset portion 29, whereas Fig. 55b illustrates a wider gusset portion 29. The gusset portion 29 would allow articulation of the nozzle 17 as well as provide upward pressure of the nozzle 17 into the patient's nasal passage. That is, the gusset portion 29 allows the change in sealing force to be in accordance with the change in treatment pressure.

[00114] As shown in Figs. 56a and 56b, each nozzle 17 may include a dual wall construction. Specifically, the nozzle 17 includes a thin membrane 124 that surrounds the upper nozzle portion 21 to enhance the seal of the nozzle 17 with the patient's nasal passage. As illustrated, the upper nozzle portion 21 may include one or more openings 126 for air communication to improve inflation of the membrane 124. The openings 126 may have any suitable shape, e.g., ring-like, and may have any suitable size. Also, as shown in Fig. 56b,

each nozzle 17 may include a gusset portion 29 in the conduit 19 that interconnects the nozzle portion 21 with a cushion. Further, both embodiments may include more than one membrane 124, thereby providing a nozzle having a three or more wall construction.

**[00115]** Figs. 57-62 illustrate embodiments of support members for supporting nozzles 17 of a patient interface and properly aligning them with the patient's nasal passages. For example, Figs. 57 and 58 illustrate a support member in the form of a C-shaped spring 130 having openings 132 for receiving nozzle conduits therein. The spring 130 is positioned between the side wall 51 of the cushion 42 and the nozzle portions 21 of the nozzles 17, and provides a biasing force to extend the nozzles 17 and maintain a substantially rigid configuration to facilitate proper alignment and seal with the patient's nasal passages. The spring 130 may be constructed of any suitable material, e.g., metal or polymer. Also, additional adjustment may be added to the spring, e.g., additional bending axis 131 that allows lateral adjustment of the nozzles.

**[00116]** Figs. 59 and 60 illustrate a support member in the form of an adjustable slider mechanism 134 having a mounting portion 135 and a support portion 136 with openings 137 for receiving nozzle conduits therein. The mounting portion 135 is secured to the frame 38 of the patient interface, e.g., by a fastener, and the support portion 136 is engaged with the nozzle portions 21 to extend the nozzles 17 and maintain a substantially rigid configuration to facilitate proper alignment and seal with the patient's nasal passages. As illustrated, the opening 138 in the mounting portion 135 for receiving the fastener is elongated, which allows adjustment of the mechanism 134 with respect to the nozzles 17. Also, additional adjustment may be added to the mechanism, e.g., additional bending axis 131 that allows lateral adjustment of the nozzles and bending axis 133 to change the angle of contact between the nozzles and patient.

[00117] Figs. 61 and 62 illustrate a support member in the form of a wedge 140 having openings 142 for receiving nozzle conduits therein. The wedge 140 is positioned between the side wall 51 of the cushion 42 and the nozzle portions 21 of the nozzles 17, and extends the nozzles 17 and maintains a substantially rigid configuration to facilitate proper alignment and seal with the patient's nasal passages. The wedge 140 may have various angles and thicknesses to achieve the optimal alignment and seal of the nozzles 17. Also, additional adjustment may be added to the wedge, e.g., additional bending axis 131 that allows lateral adjustment of the nozzles. Further, the wedge 140 may be constructed of any suitable material, e.g., foam, rigid plastic, elastomeric material such as silicone.

[00118] Figs. 63 and 64 illustrate an embodiment of a patient interface having a cushion 42 and a pair of nozzles 17 mounted to the cushion 42. As illustrated, the cushion 42 is shaped as a boomerang, and may include rims 53 extending from the side wall of the cushion 42.

[00119] Figs. 65a-65c illustrate an embodiment of a patient interface wherein the frame 38 includes extended portions 144 to cover the cheek regions of the patient's face. This arrangement is structured to prevent or at least control cheek blowout. Also, as illustrated, the frame 38 is structured such that inlet conduits 22 are coupled to opposing sides of the frame 38 for delivering breathable gas into the patient interface. However, one or more inlet conduits 22 may be coupled to the frame 38 in any other suitable manner, e.g., to the front of the frame.

[00120] Figs. 66a-67 illustrate an embodiment of a patient interface wherein the frame 38 includes an inlet conduit 22 coupled to one side thereof and an anti-asphyxia valve module 150 coupled to the opposite side thereof. It should be understood that the inlet conduit 22 and module 150 can be interchanged.

[00121] As shown in Fig. 66b, the anti-asphyxia module 150 includes an anti-asphyxia valve 154 that is housed within an anti-asphyxia cap 156 secured to the frame 38. As illustrated, the anti-asphyxia cap 156 includes a plurality of openings 157, and the anti-asphyxia valve 154 includes a flexible membrane 155 that is movable between operative and inoperative positions. In the inoperative position (shown in solid line in Figs. 66c and 66d), the membrane 155 is spaced from the cap 156 so that atmospheric air can pass through the openings 157. The membrane 155 is moved into the operative position (shown in dotted lines in Figs. 66c and 66d) by mask pressure and closes the openings 157 so that atmospheric air cannot pass through the openings 157. Embodiments of such anti-asphyxia valve and anti-asphyxia cap are disclosed in WO200038772, the contents of which are hereby incorporated by cross-reference.

[00122] The anti-asphyxia valve module 150 has the advantage of being in close proximity to the patient's mouth. The close proximity to the mouth improves CO<sub>2</sub> washout, is good for the stability of the system (i.e., there is not a heavy weight located at a distance from the patient interface), and is fail safe if the anti-asphyxia valve module 150 is not attached to the device. As illustrated, the frame and/or cushion may include an exhaust vent 152. Also, headgear 31 is attached to frame 38 in any suitable manner to maintain the cushion and nozzles in a desired adjusted position on the patient's face. In the illustrated embodiment, the headgear 31 includes a strap that extends below the ears and around the upper portion of the patient's neck, and a strap that extends in front of the ears and over the top of the patient's head. However, the headgear 31 may include any other suitable strap arrangement.

[00123] Figs. 68-70 illustrate an embodiment of a headgear assembly 160 removably coupled to the frame 38 of a patient interface so as to maintain the cushion and nozzles in a desired adjusted position on the patient's face. As illustrated, the headgear assembly 160

includes two straps each having an independent attachment to the frame 38. Specifically, the headgear assembly 160 includes an upper strap 161, a lower strap 162, and a connecting strap 163 that interconnects the upper and lower straps 161, 162. Each end of the upper and lower straps 161, 162 includes an attachment member 164 adjustably secured thereto. Each attachment member 164 is interlockable with a respective anchor 165a, 165b provided on the frame 38 as discussed in greater detail below.

[00124] As best shown in Figs. 68 and 70, each attachment member 164 includes a crossbar 166 that enables respective end portions of the straps to be wrapped around, in a known manner. The free ends of the straps include a strip of hook material 167 attached thereto by stitching, for example, that engages the loop material of the remainder of the strap to secure the attachment member in place. The hook/loop arrangement, e.g., Velcro®, allows adjustment of the straps with respect to the attachment member 164. Each attachment member 164 is in the form of a female connector that includes a relatively large lead-in opening 168a that leads into a relatively smaller attachment opening 168b.

[00125] The frame includes a main body and side frame member provided on each lateral side of the main body. The main body includes an aperture that is coupled to an inlet conduit (22) for delivering breathable gas. Upper and lower anchors 165a, 165b on each side thereof. As best shown in Fig. 69, each anchor is in the form of a male connector, e.g., protruding knob. In use, each attachment member 164 is interlocked with a respective anchor 165a, 165b by first moving the attachment member 164 adjacent the respective anchor 165a, 165b such that the respective anchor 165a, 165b extends through the larger opening 168a, and then the attachment member 164 is moved to interlock the respective anchor 165a, 165b with the smaller opening 168b. As shown in Fig. 68, the attachment members 164 on the ends of the lower strap 162 are adapted to releasably interlock with respective lower anchors 165b on the



frame 38, and the attachment members 164 on the ends of the upper strap 161 are adapted to releasably interlock with respective upper anchors 165a on the frame 38. As shown in Fig. 70, a soft flexible finger tab 169 is provided on the end of each attachment member 164 to facilitate engagement and disengagement of the attachment member 164 to the frame 38. As illustrated, the free end of the finger tab 169 may include a ball-like shape.

[00126] When mounted, each attachment member 164 is substantially flush with the frame 38. As a result, this arrangement provides no protrusions that can lead to inadvertent disengagement of the straps. Also, there are no obstructions to the patient, e.g., when sleeping on his/her side.

[00127] Also, the arrangement enables intuitive and dexterous attachment movement, permits quick release of the patient interface, and the attachment member 164 may be freely rotated with respect to the anchor 165a, 165b to allow the patient interface to self-align on the patient's face.

[00128] When mounted on a patient, the upper and lower straps 161, 162 follow two vectors to effect mask stability. Specifically, the lower strap 162 extends below the ears and around the upper portion of the patient's neck and the upper strap 161 extends over the ears and around a top portion of the patient's head. The connecting strap 163 extends along the rear portion of the patient's head, which holds the lower strap 162 in place during head rotation. One or more of the straps may be flared, e.g., at the rear, in order to better conform with the contours of the patient's head which helps reduce head pressure from strap tension.

[00129] The above arrangement enables the patient interface to be balanced, e.g., by tuning the patient interface so that sufficient pressure is applied to regions of the cushion and nozzles so an adequate seal is attained. Also, the above arrangement positions the straps away from patient's face.

[00130] Figs. 71-73 illustrate another embodiment of a headgear assembly 170 removably coupled to the frame 38 of a patient interface. As illustrated, the headgear assembly 170 includes two straps each having an independent attachment to the frame 38. Specifically, the headgear assembly 170 includes an upper strap 171 and a lower strap 172. Each end of the upper strap 171 includes an upper locking clip 173a secured thereto and each end of the lower strap includes a lower locking clip 173b secured thereto. Each locking clip 173a, 173b is interlockable with a respective clip receiver 174a, 174b provided on the frame 38 as discussed in greater detail below.

[00131] As illustrated, each upper clip 173a includes a crossbar 175 that enables respective end portions of the upper straps 171 to be wrapped around, in a known manner. In the illustrated embodiment, each free end of the upper strap 171 is secured to the remainder of the strap, e.g., by stitching, to secure the clip in place. Also, an intermediate portion of the upper strap 171 includes an adjustable ladder lock arrangement 176 for adjustment purposes. Each lower clip 173b includes an adjustable ladder lock arrangement 177 that enables respective end portions of the lower strap 172 to be engaged, in a known manner. Each free end of the lower strap 172 is held in place to the remainder of the strap by a watch strap style retainer 178. However, the straps may be secured to the clips 173a, 173b in any other suitable manner, e.g., Velcro®. Further, each clip 173a, 173b includes a side wall having a longitudinally extending slot 180 that leads into a transversely extending slot 181.

[00132] The frame 38 includes upper and lower clip receivers 174a, 174b on each side thereof. As best shown in Fig. 73, each clip receiver 174a, 174b includes a resiliently flexible tab 182 having a ramped surface leading to a locking shoulder 183 and a release projection 184. In use, each clip 173a, 173b is interlocked with a respective clip receiver 174a, 174b by first moving the clip receiver 174a, 174b into the respective clip 173a, 173b such that the

release projection 184 extends through the longitudinally extending slot 180 until the locking shoulder 183 interlocks with the transversely extending slot 181 with a snap fit. The clip 173a, 173b may be released from the respective clip receiver 174a, 174b by depressing the release projection 184 until the locking shoulder 183 releases from the transversely extending slot 181. As shown in Fig. 71, the lower clips 173b on the ends of the lower strap 172 are adapted to releasably interlock with respective lower clip receivers 174b on the frame 38, and the upper clips 173a on the ends of the upper strap 171 are adapted to releasably interlock with respective upper clip receivers 174a on the frame 38. The clip arrangement may provide audible feedback when the clip 173a, 173b is attached to the respective clip receiver 174a, 174b.

[00133] Also, as shown in Fig. 73, each clip 173a, 173b may be rotatably engaged with the respective strap such that the clip 173a, 173b may be freely rotated with respect to the strap to allow the patient interface to self-align on the patient's face.

[00134] Similar to the above-described headgear arrangement, the lower strap 172 extends below the ears and around the upper portion of the patient's neck and the upper strap 171 extends over the ears and around a top portion of the patient's head.

[00135] Figs. 74-76 illustrate another embodiment of a headgear assembly 190 removably coupled to the frame 38 of a patient interface. As illustrated, the headgear assembly 190 includes two straps with a single point of attachment to the frame 38. Specifically, the headgear assembly 190 includes an upper strap 191 and a lower strap 192. One end of the upper and lower straps 191, 192 is adjustably secured to one attachment member 193, and the other end of the upper and lower straps 191, 192 is adjustably secured to another attachment member 193. Each attachment member 193 is interlockable with a respective anchor 194 provided on the frame 38 as discussed in greater detail below.

[00136] As best shown in Fig. 76, each attachment member 193 is generally V-shaped and includes a upper and lower crossbars 195a, 195b that enable respective end portions of the straps 191, 192 to be wrapped around; in a known manner. The free ends of the straps 191, 192 include a strip of hook material attached thereto by stitching, for example, that engages the loop material of the remainder of the strap to secure the attachment member in place. The hook/loop arrangement, e.g., Velcro®, allows adjustment of the straps 191, 192 with respect to the attachment member 193. However, the straps 191, 192 may be secured to the attachment member 193 in any other suitable manner, e.g., adjustable ladder-lock arrangement. Each attachment member 193 includes a relatively large lead-in into a relatively smaller attachment opening 196.

[00137] The frame includes an anchor 194 on each side thereof. As best shown in Fig. 75, each anchor 194 is in the form of a protruding knob. Moreover, each anchor 194 is mounted on a sliding adjustment mechanism that allows sliding adjustment of the anchor 194 between upper and lower portions of the frame 38. Specifically, the anchor 194 is mounted on a slide 197 that is movable by a button 198 by sliding the button 198 within a slot to adjust the anchor height. The adjustment mechanism may be held in position by, e.g., frictional engagement, detents that would allow for discrete steps of movement.

[00138] In use, each attachment member 193 is interlocked with a respective anchor 194 by first moving the attachment member 193 adjacent the respective anchor 194 such that the anchor 194 extends through the lead-in, and then the attachment member 193 is moved to interlock the anchor 194 with the smaller attachment opening 196. As shown in Fig. 76, a spring mechanism 199 may be incorporated into the opening 196 so that the connection does not wear. As shown in Fig. 74, each end of the frame 38 interlocks with a respective attachment member 193, and each attachment member 193 secures ends of the respective

upper and lower straps 191, 192. As illustrated, a soft flexible finger tab 200 is provided on the end of each attachment member 193 to facilitate engagement and disengagement of the attachment member 193 to the frame 38. As illustrated, the free end of the finger tab 200 may include one or more protrusions for finger grip. Also, the headgear straps 191, 192 are preferably elastic to help with fitting.

[00139] The arrangement enables intuitive and dexterous attachment movement, permits quick release of the patient interface, and the attachment member 193 may be freely rotated with respect to the anchor 194 to allow the patient interface to self-align on the patient's face.

[00140] Similar to the above-described headgear arrangements, the lower strap 192 extends below the ears and around the upper portion of the patient's neck and the upper strap 191 extends over the ears and around a top portion of the patient's head.

[00141] Figs. 77 and 78 illustrate another embodiment of a headgear assembly 210 removably coupled to the frame 38 of a patient interface. As illustrated, the headgear assembly 210 includes two straps with a single point of attachment to the frame 38. Specifically, the headgear assembly 210 includes an upper strap 211 and a lower chin strap 212. One end of the upper and lower straps 211, 212 is adjustably secured to one attachment member 213, and the other end of the upper and lower straps 211, 212 is adjustably secured to another attachment member 213. Each attachment member 213 is interlockable with a respective anchor 214 provided on the frame 38 as discussed in greater detail below.

[00142] As best shown in Fig. 78, each attachment member 213 includes an upper clip receiver 215 and a lower crossbar 216. As illustrated, end portions of the upper strap 211 are secured to respective locking clips 217 (e.g., strap wrapped around clip cross-bar and free end of the strap is secured to the remainder of the strap by Velcro® arrangement), which are releasably interlocked with a respective upper clip receiver 215. The interlocking

engagement may be similar to the snap-fit clip arrangement disclosed in Figs. 71-73.

Respective end portions of the lower strap 212 are wrapped around a respective lower cross-bar 216, in a known manner. The free ends of the lower straps 212 may engage the remainder of the strap via a Velcro® arrangement. Each attachment member 213 also includes a relatively large lead-in into a relatively smaller attachment opening 218.

[00143] The frame 38 includes an anchor 214, e.g., in the form of a protruding knob, on each side thereof. The anchors 214 may be mounted on a sliding adjustment mechanism similar to that shown in Figs. 74 and 75. In use, each attachment member 213 is interlocked with a respective anchor 214 by first moving the attachment member 213 adjacent the respective anchor 214 such that the anchor 214 extends through the lead-in, and then the attachment member 213 is moved to interlock the anchor 214 with the smaller attachment opening 218. As shown in Fig. 78, a spring mechanism 219 may be incorporated into the opening 218 so that the connection does not wear. As shown in Fig. 77, each end of the frame 38 interlocks with a respective attachment member 213, and each attachment member 213 secures ends of the respective upper and lower straps 211, 212. As illustrated, a soft flexible finger loop 220 is provided on the side of each attachment member 213 to provide a means for quick disengagement of the attachment member 213 from the frame 38. Also, the headgear straps 211, 212 are preferably elastic to help with fitting.

[00144] The arrangement enables intuitive and dexterous attachment movement, permits quick release of the patient interface, and the attachment member 213 may be freely rotated with respect to the anchor 214 to allow the patient interface to self-align on the patient's face.

[00145] When mounted on a patient, the lower strap 212 extends downwardly and around the patient's chin and the upper strap 211 extends over the ears and around a top portion of the patient's head.

[00146] Figs. 79-80 illustrate another embodiment of a headgear assembly 230 removably coupled to the frame 38 of a patient interface. As shown in Fig. 79, the headgear assembly 230 includes an upper strap 232 and a lower strap 234. However, the lower strap 234 is optional. Also, the strap may have two-strap configuration wherein upper and lower straps 232, 234 are incorporated into a single structure as shown in Fig. 80. Each end of the straps includes an attachment member 236 adjustably secured thereto. Each attachment member 236 is interlockable with a respective anchor 238a, 238b provided on the frame 38 as discussed in greater detail below.

[00147] Each attachment member 236 may be secured to a respective end of the strap in any suitable manner, e.g., stitching, Velcro®. Also, each attachment member 236 includes an attachment opening.

[00148] The frame 38 includes upper and lower anchors 238a, 238b on each side thereof. Each anchor 238a, 238b is in the form of a protruding knob. In use, each attachment member 236 is interlocked with a respective anchor 238a, 238b by moving the attachment member 236 adjacent the respective anchor 238a, 238b such that the respective anchor 238a, 238b extends through the attachment opening.

[00149] As shown in Fig. 79, the upper anchor 238a is mounted on a rotatable plate 240 that allows the position of the upper anchor 238a to be rotatably adjusted. This arrangement allows the angle of the patient interface with respect to the patient's face to be adjusted. Moreover, the arrangement allows the headgear assembly 230 to remain in the same position relative to the patient's head even as the angle of the patient interface changes. Rotation may be discrete with specific indexed positions, or rotation may be continuous with the desired position being maintained by friction.

[00150] A soft flexible finger tab 242 is provided on the end of each attachment member 236 to facilitate engagement and disengagement of the attachment member 236 to the frame 38.

As illustrated, the free end of the finger tab 242 may include one or more gripping protrusions.

[00151] Also, all the headgear assemblies described above may incorporate rigidizing elements (via insertion of rigid panels, stitching, lamination, or other means) to add rigidity to the headgear assemblies to aid in mask stability.

[00152] It should be understood that the cushion 42 and nozzles 17 described above may be formed from any suitable material. For example, the cushion 42 and nozzles 17 may be formed from a gel-like material, or they may be formed from a foam-like material. Also, the cushion 42 and nozzles 17 may be formed separately from one another, or may be integrally formed as a one-piece structure.

[00153] Further, although the above embodiments are described in relation to nozzles, nasal prongs (which are inserted into the nose) and/or nasal dilators are also contemplated.

[00154] Advantages of illustrated preferred embodiments may include:

- reducing significantly the bulk required to form an effective nasal and oral seal. This has the advantage of creating a less intrusive patient interface that significantly reduces the problems of patient claustrophobia. The removal of the requirement to seal around the nasal bridge provides the opportunity for the patient to wear spectacles. In addition this removes the danger of leaks affecting the sensitive eye region, thereby reducing the possibility of creating conjunctivitis style problems.
- reducing the force (headgear tension) required to maintain the seal as compared to current full face masks in the prior art. The force is reduced due to the reduction in the



effective area of the cushion on to the face. As a result, there is less area over which the pressure inside the patient interface acts and the resultant headgear tension is reduced.

- improving seal as it avoids the nose bridge region where leak commonly occurs, thus the force required to deform the cushion and effect a seal is also reduced. The reduction in the headgear tension and cushion to face force would substantially reduce the discomfort to a patient.

[00155] The reduction in the area of the face across which a seal must be formed allows a single size or shape to fit a wider range of patient geometry. This is particularly advantageous for a clinician since the patient interface is both easier to fit to a new patient and potentially more forgiving of fitting errors. The independent nature of the chambers due to the flexible connection, also allows for some movement of the face during the night without loss of seal. This leads to far more stability than conventional single chamber full face masks.

[00156] The provision of flexibility allows the seal to remain throughout jaw and head position movement as well as providing adjustment for the different geometry of a wide range of patients. The task of fitting varying patient geometry is made easier by the removal of the need to seal around the complex form of the nasal bridge which is found in most of the prior art masks that seal both the nasal and oral passages. The lack of seal around the nasal bridge also allows the patient to wear spectacles.

[00157] Although the invention has been described with reference to the illustrated embodiments, it is to be understood that the illustrated embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.